

## CLAIMS

That which is claimed is:

1. A cap for a dermal tissue lancing device, the dermal tissue lancing device including a housing and a lancet that is movable with respect to the housing, the cap comprising:

a proximal end for engaging with the housing;

a distal end for engaging with dermal tissue; and

an opening for a portion of the lancet to pass through;

wherein the distal end includes at least a first portion and a second portion for engaging dermal tissue, the at least first and second portions being resiliently deformable such that, when the cap contacts and is urged towards dermal tissue, the at least first and second portions deform resiliently, engage the dermal tissue and approach theretogether.

2. The cap of claim 1 in which at least one of the first portion and second portion includes an edge portion that serves to define a part of the opening.

3. The cap of claim 1, wherein the at least first and second portions are adapted such that when the cap contacts and is urged toward dermal tissue, the at least first and second portions deform resiliently such that the opening is reduced in size.

4. The cap of claim 1 in which the at least first and second portions form a continuous ring adapted for engaging and surrounding dermal tissue.

5. The cap of claim 4, wherein the continuous ring is substantially circular.

6. The cap of claim 1 in which the cap is at least partially formed of a resilient, deformable material.

7. The cap of claim 6, wherein the cap is formed from a resilient deformable material selected from the group consisting of elastomeric materials, polymeric materials, polyurethane materials, latex materials, silicone materials, and combinations thereof.

8. The cap of claim 1, wherein the cap is formed of a material sufficiently transparent to distinguish a fluid sample to be withdrawn with the dermal tissue lancing device.

9. The cap of claim 1 formed of a non-blood colored material.

10. The cap of claim 1, wherein the cap is of a graded resilience such that the distal end is more resilient than the proximal end.

11. The cap of claim 1, wherein the cap is at least partially formed of an anti-microbial material.

12. The cap of claim 11, wherein the anti-microbial material includes a trichloro-phenol compound.

13. The cap of claim 12, wherein the trichloro-phenol compound is 2,4,4-Trichloro-2-hydroxy-diphenol.

14. The cap of claim 1, wherein the cap includes a coating of anti-microbial material.

15. The cap of claim 1, wherein the at least first and second portions are inwardly bendable portions.

16. The cap of claim 15, wherein the inwardly bendable portions include skin-gripping teeth.

17. The cap of claim 1, wherein the at least first and second portions have a six-sided cross-section.

18. The cap of claim 1, wherein the at least first and second portions have a six-sided cross-section, the cross-section including an internal angle that determines a compressed position of the cap during use.

19. The cap of claim 1, wherein the cap is configured to be stackable with other identical caps.

20. The cap of claim 1, wherein the at least first and second portions deform resiliently, engage the dermal tissue and approach theretogether such that a bulge is created in the dermal tissue.

21. The cap of claim 20, wherein the cap is configured for applying a pre-lance pressure to maintain the bulge prior to lancing by the dermal tissue lancing device and for applying a post-lance pressure to further maintaining the bulge after lancing by the dermal tissue lancing device.

22. A cap for a dermal tissue lancing device, the dermal tissue lancing device including a housing and a lancet that is movable with respect to the housing, the cap comprising:

a proximal end for engaging with the housing;

a distal end for engaging with dermal tissue; and

an opening for a portion of the lancet to pass through;

wherein the distal end includes at least a first portion and a second portion for engaging dermal tissue, the at least first and second portions being resiliently deformable such that, when the cap contacts and is urged towards dermal tissue, the at least first and second portions deform resiliently such that the opening is reduced in size, engage the dermal tissue and approach theretogether.

23. A cap for a dermal tissue lancing device, the dermal tissue lancing device including a housing and a lancet that is movable with respect to the housing, the cap comprising:

a cap body;

a retainer; and

an opening for a portion of the lancet to pass through;

wherein the cap body has a proximal end for engaging with the retainer and a distal end for engaging with dermal tissue; and

wherein the retainer has a proximal end for engaging with the housing and a distal end for engaging with the cap body; and

wherein the distal end of the cap body includes at least a first portion and a second portion for engaging dermal tissue, the at least first and second portions being resiliently deformable such that, when the cap contacts and is urged towards dermal tissue, the at least first and second portions deform resiliently, engage the dermal tissue and approach theretogether.

24. The cap of claim 23, wherein the proximal end of the cap body is prevented by the retainer from deforming outwardly in a plane substantially parallel to a plane containing the opening.

25. The cap of claim 23, wherein the proximal end of the cap body freely rests within the retainer.

26. The cap of claim 23, wherein the proximal end of the cap body is fixedly mounted to the retainer.

27. The cap of claim 23, wherein the retainer includes a stop for preventing deformation of the cap body in a direction generally perpendicular to a plane containing the opening.

28. The cap of claim 23, wherein a cross-sectional shape of the cap is such that a pivot is formed on the cap body and within the retainer such that when the cap, including the cap body and retainer, is urged towards dermal tissue the cap body pivots within the retainer such that the size of the opening is reduced.

29. The cap of claim 23, wherein a cross-sectional shape of the cap body is such that when the cap is urged towards the dermal tissue of a user, the cap body experiences one of falling and folding in on itself once a predetermined urging force is applied, thereby reducing the size of the opening.

30. The cap of claim 29, wherein the cap body includes at least one weak region so as to enable the cap body to fold in on itself once the predetermined force is applied.

31. The cap of claim 23, wherein the cap body and retainer are formed as an integral unit.

32. The cap of claim 23, wherein the size of the opening is reduced once the cap has been urged towards dermal tissue.

33. The cap of claim 23, wherein the retainer has an inwardly facing recess for receiving the cap body and an inwardly protruding rim configured to operatively cooperate with an the outer surface of the cap body.

34. The cap of claim 23, wherein the cap body is a flexible cap body.

35. A lancet device comprising:

a housing;

a lancet that is moveable with respect to the housing; and

a cap that includes:

a proximal end for engaging with the housing;

a distal end for engaging with dermal tissue; and

an opening for a portion of the lancet to pass through;

wherein the distal end includes at least a first portion and a second portion for engaging dermal tissue, the at least first and second portions being resiliently deformable such that, when the cap contacts and is urged towards dermal tissue, the at least first and second portions deform resiliently, engage the dermal tissue and approach theretogether.

36. The lancet device of claim 35, wherein the cap includes:

a flexible cap body; and

a retainer.

37. A combined lancet and metering device for lancing dermal tissue, extracting a fluid sample and measuring an analyte within said fluid sample, the combined lancet and metering device comprising:

a housing;

a lancet that is moveable with respect to the housing;

a cap that includes:

a proximal end for engaging with the housing;

a distal end for engaging with dermal tissue; and

an opening for a portion of the lancet to pass through;

wherein the distal end includes at least a first portion and a second portion for engaging dermal tissue, the at least first and second portions being resiliently deformable such that, when the cap contacts and is urged towards dermal tissue, the at least first and second portions deform resiliently, engage the dermal tissue and approach theretogether; and

a metering device for measuring the analyte within the fluid sample.

38. A combined lancet and metering device for lancing dermal tissue, extracting a fluid sample and measuring an analyte within the fluid sample in which a fluid collection device is delivered to a position adjacent a lancing position after lancing has occurred such that the fluid sample can be collected and measured within the metering device without repositioning of the combined lancet and metering device with respect to the puncture, the combined lancet and metering device comprising:

a housing;

a lancet that is moveable with respect to the housing; and

a cap that includes:

a proximal end for engaging with the housing;

a distal end for engaging with dermal tissue; and

an opening for a portion of the lancet to pass through;

wherein the distal end includes at least a first portion and a second portion for engaging dermal tissue, the at least first and second portions being resiliently deformable such that, when the cap contacts and is urged towards dermal tissue, the at least first and second portions deform resiliently, engage the dermal tissue and approach theretogether.

39. The combined lancet and metering device of claim 38, wherein the fluid collection device is a test strip.

40. A method for the collection of a fluid sample from dermal tissue, the method comprising:

providing a dermal tissue lancing device that includes:

a housing;

a lancet that is moveable with respect to the housing; and

a cap that includes:

- a proximal end for engaging with the housing;
- a distal end for engaging with dermal tissue; and
- an opening for a portion of the lancet to pass through;

wherein the distal end includes at least a first portion and a second portion for engaging dermal tissue, the at least first and second portions being resiliently deformable;

contacting the cap with the dermal tissue such that the at least first and second portions engage the dermal tissue;

urging the cap towards the dermal tissue such that the at least first and second portions deform resiliently and approach theretogether, thereby creating a bulge in the dermal tissue;

lancing the bulge using the lancet to create a puncture in the bulge; and

collecting a fluid sample from the puncture.

41. The method of claim 40, wherein the urging step decreases the size of the opening due to the approaching theretogether of the at least first and second portions.

42. The method of claim 40, wherein the collecting step includes collecting a blood sample from the puncture.

43. The method of claim 40 further including:

applying pre-lance pressure to the dermal tissue by holding the cap against the dermal tissue following the urging step and prior to the lancing step, thereby maintaining the bulge.

44. The method of claim 40 further including: and

applying a post-lance pressure to the dermal tissue by holding the cap against the dermal tissue following the lancing step, thereby further maintaining the bulge.



45. The method of claim 44, wherein the applying of the post-lance pressure occurs for a predetermined time of approximately 5 seconds.

46. A method for the collection of a fluid sample from dermal tissue, the method comprising:

providing a dermal tissue lancing device that includes:

a housing;

a lancet that is moveable with respect to the housing; and

a cap that includes:

a proximal end for engaging with the housing;

a distal end for engaging with dermal tissue; and

an opening for a portion of the lancet to pass through;

wherein the distal end includes at least a first portion and a second portion for engaging dermal tissue, the at least first and second portions being resiliently deformable;

contacting the cap with the dermal tissue such that the at least first and second portions engage the dermal tissue;

urging the cap towards the dermal tissue such that the at least first and second portions deform resiliently and approach theretogether, thereby creating a bulge in the dermal tissue;

lancing the bulge using the lancet to create a puncture in the bulge;

applying a post-lance pressure to the dermal tissue by holding the cap against the dermal tissue, thereby further maintaining the bulge; and

collecting a fluid sample from the puncture.